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PRINCIPAL INVESTIGATOR: David Klonoff, M.D.

CONTRACTING ORGANIZATION: Diabetes Technology Society
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POST MEETING REPORT
SECOND ANNUAL CLINICAL DIABETES TECHNOLOGY MEETING
APRIL 21-22, 2006
CAMBRIDGE, MASSACHUSETTS

The Second Annual Clinical Diabetes Technology Meeting was presented by the Diabetes Technology Society at the Cambridge, Massachusetts Hyatt Regency Hotel in April 21-22, 2006. The first day covered Continuous Glucose Monitoring and the second day covered Insulin Delivery Strategies. The attendees consisted of 405 clinicians and scientists.

On April 21, 2006, which was the Continuous Glucose Monitoring day, the first presentation was made together by Lori Laffel, MD and David Klonoff, MD on the topic, "Benefits and Limitations of Intermittent Blood Glucose, A1c, and Ketone Testing". These two clinicians emphasized the need for regular home blood glucose and Hemoglobin A1c monitoring of patients with diabetes, as well as measurement of blood ketones in situations of suspected ketoacidosis. From a literature review, the frequency of self-blood glucose monitoring was demonstrated to be inversely associated with improved glycemic control. For every additional blood glucose measurement, the Hemoglobin A1c level tends to fall by approximately 0.3%. Parallels between monitoring technologies relevant to patients with diabetes as well as to warfighters were mentioned. Barry Ginsberg, MD, PhD discussed continuous glucose monitoring technologies. He emphasized that this technology can be used to predict abnormal glucose levels based on patterns of glycemia. Lawrence Blonde, MD discussed "HbA1C, Glycemic Variability (Stability) and Other Outcome Markers – What is the Most

initiating pramlintide therapy to minimize the risk of postprandial hypoglycemia. John Buse, MD, PhD discussed another new drug. His presentation was entitled, "Exenatide (Byetta®) and Other Incretin Mimetic Therapies – A Look at Changing Treatment Paradigms." He described how a gastrointestinal hormone, glucagon-like peptide-1, can decrease appetite, improve pancreatic insulin production, decrease pancreatic glucagon production, and slow gastric emptying to effect lower blood glucose levels in Type 2 diabetes. He emphasized the excellent safety profile of this drug and its potential to promote weight loss in obese patients with Type 2 diabetes. Suzanne Ghiloni, RN presented an overview of the latest devices for managing diabetes entitled, "Technology Update – Insulin Pens, Smart Pumps, Disposable Pumps, and Data Management". She showed examples of insulin pens, insulin pumps, and software programs for determining insulin dosages. A debate was held between Satish Garg, MD and Steven Wittlin, MD about advantages and disadvantages of using an insulin pump compared to basal insulin injections along with multiple dosages of mealtime bolus insulin in Type 1 diabetes. Both participants agreed that there were benefits to insulin pump therapy, however they disagreed on the importance and relative economic benefits of the additional benefits that are provided by insulin pump therapy. Dr. Garg favored use of basal plus bolus therapy for most patients and Dr. Wittlin favored the use of an insulin pump for most patients. Neither debater backed down in response to evidence from the other debater. The final presentation of the day was a discussion of current and future trends in diabetes technology led by Stuart Weinzimer, MD. The participants included Darrell Wilson, MD, Michael Bryer-Ash, MD, and Daniel Crowe, MD. They discussed the need for better

In the ICU and the Wards". He pointed out the abnormal physiological state of being either a preoperative and postoperative patient, and he discussed the risks of perioperative complications in patients whose hyperglycemia is not aggressively treated. He pointed out how the two risk factors of first, frequent underdosing of intravenous glucose in the operating room and second, glycogen depletion due to perioperative malnutrition can combine to increase the risk of postoperative hypoglycemia. This risk is present in addition to the risk of postoperative hyperglycemia due to insulin resistance from stress hormones that are produced during surgery. David Baldwin, Jr., MD discussed how to "Eliminate Sliding scale Insulin in the Hospital". He presented a regimen perfected at Rush University that combines basal and bolus insulin therapy instead of depending solely on bolus sliding scale insulin. The incidence of severe hyperglycemia has decreased with institution of this program administered by House Officers at his University Hospital. William Cefalu, MD presented an overview of inhaled insulin therapy entitled, "Inhaled Insulin – An Update and A Look Forward". He reviewed the safety and efficacy of administering insulin via this route and concluded that inhaled insulin will be a viable and widely adopted therapeutic option in the future. Other medications or vaccinations that are currently available only by the way of injection may eventually become available in inhaled preparations, which will facilitate their use, especially in ssituation where immediate use is required. Diane Karl, MD discussed a new drug in a talk entitled, "Therapeutics of Pramlintide (Symlin) in Type 1 diabetes". She pointed out how this hormone's mechanism of action on the brain and stomach has resulted in slowing of gastric emptying and evening out of postprandial hyperglycemia. She pointed out that it is necessary to decrease the dose of mealtime insulin when

continuous glucose monitor could be incorporated into this device, which is still currently under development, so that injured warfighters being evacuated from the battlefield to distant hospital can be treated for stress-hyperglycemia. Finally a patient panel was convened. Six patients with diabetes discussed their experiencesd wearing continuous glucose monitors. The patients and two panel moderators all agreed that this monitoring technology provides valuable information that spot blood glucose monitoring cannot deliver.

On April 22, 2006, which was the Insulin delivery strategies day, the first presentation was made by Chan Coopan, MD on the topic, "Treatment goals and strategies for Type 2 diabetes – the changing landscape". He discussed the need for aggressive treatment of not only elevated glucose levels, but of elevated blood pressure and lipid levels in Type 2 diabetes. Michael Bryer-Ash, MD then presented the first of four discussions of in-hospital management of diabetes. He reviewed the evidence for maintaining control of blood glucose levels in acutely ill hospitalized patients, including those with no known prior history of diabetes. He pointed out that consensus statements by clinical endocrinology organizations have stressed the need for improved management of inpatient hyperglycemia. Steven Clement, MD next discussed "Algorithms for Intensive Insulin Therapy of Diabetes in the Hospital - In the ICU and the Wards". He presented a variety of insulin-dosing algorithms that are used at Georgetown University Hospital and other major hospitals. He showed how a hospital can develop its own set of orders for maintaining tight control of hyperglycemia in hospitalized patients. Jeffrey Joseph, DO then discussed, "Algorithms for Intensive Insulin Therapy of Diabetes in the Hospital -

Telling?" disparities between estimates of glycemia using an integrated measure such as Hemoglobin A1c and measurements of glycemic variability. Howard Wolpert, MD discussed "Using CGM in Diagnosing and Managing Hypoglycemia Unawareness". He described how the use of continuous glucose monitoring necessitates proper patient education to minimize the risk for hypoglycemia from excessive uncontrolled post-prandial dosing, also known as insulin stacking. Darrell Wilson, MD spoke on the "Impact of Real Time Continuous Readings on Children and Their Families". He pointed out that two important problems in utilizing continuous glucose monitoring safely and effectively in children are first to select patients properly and second to establish individualized regimens for a frequency and duration of sensor wear. Irl Hirsch, MD spoke on "Algorithms for Care in Adults Using CGM". He stated that instead of considering blood glucose readings only as a stagnant number, it will be necessary to develop algorithms based on dynamic glycemic trending. Such algorithms will be individually created based on each patient's carbohydrate and insulin sensitivities, the type of food recently eaten, and the exercise performed, as well as the amount of insulin on board. The clinically relevant topic for clinicians, "What will it take to get CGM reimbursed – Examining compelling factors" was discussed by Claudia Graham, PhD, Virginia Tobiason, RN, and Charles Raine, III, MD. They reviewed the process for a new product containng a new technology to receive coding, coverage and reimbursement. COL Karl Friedl, PhD, the Commander of United States Army Research Institute of Environmental Medicine, described the US Army's program for physiological monitoring of warfighters program and then presented an example of a non-implanted multiparameter physiological monitoring system with capability for remote data transmission. He stated that a

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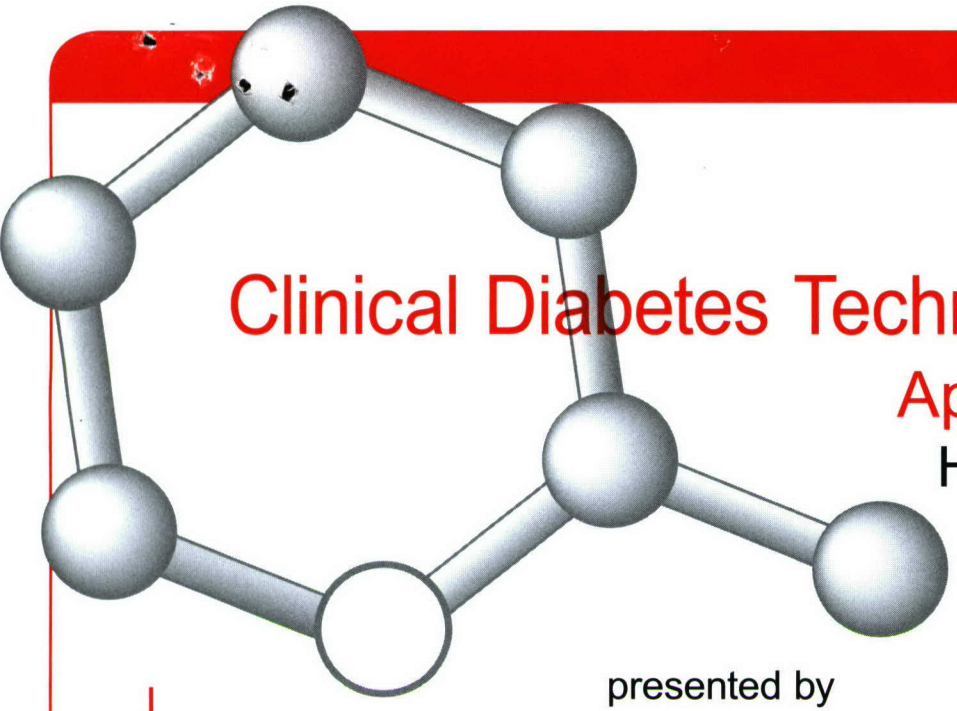


Second Annual

Clinical Diabetes Technology Meeting

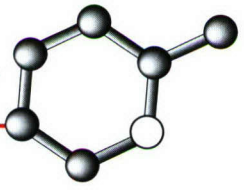
April 21 & 22, 2006

Hyatt Regency Hotel Cambridge

presented by

DIABETES TECHNOLOGY SOCIETY

Applying science and engineering to fight diabetes



Developed in cooperation with:

- Barbara Davis Center for Childhood Diabetes
- Stanford University, Department of Pediatrics
- Yale University, Department of Pediatrics
- University of California at San Francisco, Diabetes Center
- Pennsylvania State University, Department of Medicine
- Technologies for Metabolic Monitoring Research Program
- U.S. Army Research Institute of Environmental Medicine
- Mills-Peninsula Health Services
- Medical Education Collaborative

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- Bayer Healthcare: Diabetes Care
- Becton, Dickinson and Company
- LifeScan, Inc.
- Medtronic MiniMed
- Novo Nordisk A/S
- sanofi aventis

Planning Committee:

- David Klonoff, M.D., FACP, Chair
  Diabetes Research Institute, Mills-Peninsula Health Services, San Mateo, California, and Department of Medicine, University of California at San Francisco; Editor, *Journal of Diabetes Technology*
- Robert Gabbay, M.D., Ph.D.
  Department of Medicine, Pennsylvania State University, Hershey, Pennsylvania
- Satish Garg, M.D.
  Departments of Pediatrics and Medicine, Barbara Davis Center for Childhood Diabetes, University of Colorado, Aurora, Colorado
- Stephen Gitelman, M.D.
  Department of Pediatrics, University of California at San Francisco, San Francisco, California
- Jeffrey Joseph, D.O.
  Artificial Pancreas Center and Department of Anesthesiology, Thomas Jefferson University, Philadelphia, Pennsylvania
- Robert Vigersky, M.D.
  Diabetes Institute, Walter Reed Army Medical Center, Washington, DC
- Stuart Weinzimer, M.D.
  Department of Pediatrics, Yale University, New Haven, Connecticut
- Darrell Wilson, M.D.
  Department of Pediatrics, Stanford University, Palo Alto, California
- Howard A. Wolpert, M.D.
  Joslin Diabetes Center, Harvard University, Boston, Massachusetts

Diabetes Technology Society ***www.clinicaldiabetestechnology.org***

Agenda

Clinical Continuous Glucose Monitoring Session

Friday – April 21, 2006

08:00 Welcome
David Klonoff, M.D., FACP
Mills-Peninsula Health Services, San Mateo, California, and UC San Francisco

08:05 Benefits and Limitations of Intermittent Blood Glucose, A1c, and Ketone Testing
David Klonoff, M.D., FACP
Mills-Peninsula Health Services, San Mateo, California, and UC San Francisco
Lori Laffel, M.D., M.P.H.
Joslin Diabetes Center, Harvard University, Boston, Massachusetts

08:50 The Current Environment of CGM Technologies
Barry Ginsberg, M.D., Ph.D.
Becton, Dickinson and Company, Franklin Lakes, New Jersey

09:35 HbA1C, Glycemic Variability (Stability) and Other Outcome Markers – What is the Most Telling?
Lawrence Blonde, M.D., FACP
Ochsner Clinic Foundation, New Orleans, Louisiana

10:20 Break (Refreshments Provided)

10:50 Using CGM in Diagnosing and Managing Hypoglycemia Unawareness – Discussion and Demonstration
Howard Wolpert, M.D.
Joslin Diabetes Center, Harvard University, Boston, Massachusetts

11:35 Impact of Real–Time Continuous Readings on Children and Their Families
Darrell Wilson, M.D.
Stanford University, Palo Alto, California

12:20 Lunch (Provided)

13:20 Algorithms for Care in Adults Using CGM
Irl Hirsch, M.D.
University of Washington, Seattle, Washington

14:05 What Will it Take to Get CGM Reimbursed – Examining Compelling Factors
Virginia Tobiason R.N.
Abbott Laboratories, Abbott Park, Illinois
Claudia Graham, Ph.D.
Medtronic MiniMed, Northridge, California
Charles Raine, M.D.
Medical University of South Carolina, Charleston, South Carolina

14:50 Physiological Monitoring of the Warfighter
Colonel Karl Friedl, Ph.D.
Commander, United States Army Institute of Environmental Medicine, Natick, Massachusetts

15:35 Break (Refreshments Provided)

16:05 Live Demonstration of Interpreting Real Time Continuous Glucose Monitoring Data
Stuart Weinzimer, M.D.
Yale University, New Haven, Connecticut
Howard Wolpert, M.D.
Joslin Diabetes Center, Boston, Massachusetts

16:50 Patient Panel: Continuous Glucose Monitors – What We Like and Don't Like
Marilyn Ritholz, Ph.D.
Joslin Diabetes Center, Harvard University, Boston, Massachusetts
Stuart Weinzimer, M.D.
Yale University, New Haven, Connecticut

17:35 Adjourn

Agenda

Insulin Delivery Strategies Session

Saturday - April 22, 2006

08:00 Welcome
David Klonoff, M.D., FACP
Mills-Peninsula Health Services, San Mateo, California, and UC San Francisco

08:05 Treatment Goals and Strategies for Type 2 Diabetes – The Changing Landscape
Chan Cooppan, M.D.
Joslin Diabetes Center, Harvard University, Boston, Massachusetts

08:50 In-Hospital Management of Hyperglycemia - What is the Evidence?
Michael Bryer-Ash, M.D., FRCP
UCLA, Los Angeles, California

09:35 Algorithms for Intensive Insulin Therapy of Diabetes in the Hospital - In the ICU and the Wards
Moderator - Robert Vigersky, M.D.
Walter Reed Army Medical Center, Washington, DC
Stephen Clement, M.D.
Georgetown University, Washington, DC
Jeffrey Joseph, D.O.
Thomas Jefferson University, Philadelphia, Pennsylvania

10:20 Break (Refreshments Provided)

10:50 Eliminating Sliding Scale Insulin in the Hospital
David Baldwin, Jr., M.D.
Rush University, Chicago, Illinois

11:35 Inhaled Insulin – An Update and A Look Forward
William Cefalu, M.D.
Louisiana State University, Baton Rouge, Louisiana

12:20 Lunch (Provided)

13:20 Therapeutics of Pramlintide (Symlin®) in Type I Diabetes
Diane Karl, M.D.
The Endocrine Clinic, Portland, Oregon

14:05 Exenatide (Byetta®) and Other Incretin Mimetic Therapies – A Look at Changing Treatment Paradigms
John Buse, M.D., Ph.D., CDE, FACE
University of North Carolina, Chapel Hill, North Carolina

14:50 Technology Update - Insulin Pens, Smart Pumps, Disposable Pumps, and Data Management
Suzanne Ghiloni, R.N.
Joslin Diabetes Center, Harvard University, Boston, Massachusetts

15:20 Break (Refreshments Provided)

15:50 Debate – Pump vs. Basal Insulin / Advantages vs. Disadvantages
Moderator – Robert Gabbay, M.D., Ph.D.
Pennsylvania State University, Hershey, Pennsylvania
Satish Garg, M.D.
Barbara Davis Diabetes Center, University of Colorado, Aurora, Colorado
Steven Wittlin, M.D.
University of Rochester, Rochester, New York

16:50 Discussion of Current and Future Trends in Diabetes Technology
Moderator - Stuart Weinzimer, M.D.
Yale University, New Haven, Connecticut
Michael Bryer-Ash, M.D., FRCP
UCLA, Los Angeles, California
Daniel Crowe M.D.
Portsmouth Regional Hospital, Portsmouth, New Hampshire
Darrell Wilson, M.D.
Stanford University, Palo Alto, California

17:35 Adjourn

Faculty Disclosure

Second Annual Clinical Diabetes Technology Meeting: April 21& 22, 2006
Hyatt Regency Hotel, Cambridge, Massachusetts

As a sponsor accredited by the Accreditation Council on Continuing Medical Education (ACCME), Medical Education Collaborative must ensure balance, independence, objectivity, and scientific rigor in scientific educational activities. All faculty participating in a Medical Education Collaborative activity are required to disclose all commitments to or relationships with pharmaceutical companies, biomedical device manufacturers or distributors, or others whose products or services may be considered to be related to the subject matter of the scientific / educational activity. All faculty are also required to identify whether an unapproved use of products will be referenced in their presentation, such as off-label usage or pharmaceuticals or instruments.

NO ACTUAL OR POTENTIAL CONFLICT
Daniel Crowe, M.D.
Karl Friedl, Ph.D.
Suzanne Ghiloni, R.N.
Marilyn Ritholz, Ph.D.
Robert Vigersky, M.D.
Darrell Wilson, M.D.

DISCLOSED RELATIONSHIP(S) WITH INDUSTRY

David Baldwin, Jr., M.D. – Grant support from sanofi aventis; Speaker for Novo Nordisk, sanofi aventis.

Lawrence Blonde, M.D. – Investigator for Amylin, AstraZeneca, BMS, Eli Lilly, MannKind, Merck, Novo Nordisk, Novartis, Pfizer, sanofi-aventis; Consultant and Speaker for Abbott, Amylin, Eli Lilly, GSK, LifeScan, Merck/ Schering Plough, Novartis, Pfizer, sanofi aventis; Speaker for Takeda, Wyeth; Consultant for AstraZeneca.

Michael Bryer-Ash, M.D. – Speaker for Takeda-Lilly, BMS, GSK, Novartis, Novo Nordisk, sanofi aventis, Wyeth.

John Buse, M.D., Ph.D. – Grant support from Amylin, Novartis, Roche; Consultant for Amylin, Lilly.

William Cefalu, M.D. – Grant support from Pfizer, Novartis, Lilly; Consultant for Pfizer, Lilly, Merck, Amylin; Speaker for Pfizer, Lilly, Amylin.

Stephen Clement, M.D. – Grant support from Takeda; Speaker for Aventis.

Chan Coopan, MBChB., FRCP(C) - Speaker for Takeda-Lilly, BMS, GSK, Novartis, Novo Nordisk, sanofi aventis, Wyeth.

Robert Gabbay, M.D., Ph.D. – Speaker for GSK, sanofi aventis, Novo Nordisk, Pfizer, Amylin.

Satish Garg, M.D. – Grant support from Animas, Aventis, DexCom, Eli Lilly, NIH, Novo Nordisk, Roche; Consultant and Speaker for Animas, Aventis, DexCom, Eli Lilly, NIH, Novo Nordisk, Roche.

Barry Ginsberg, Ph.D. – Employee of Becton, Dickinson and Company; Major Shareholder of Becton, Dickinson and Company.

Claudia Graham, Ph.D. – Employee of Medtronic MiniMed.

Irl Hirsch, M.D. – Grant support from Medtronic MiniMed; Consultant for Abbott, Eli Lilly, Novo Nordisk and sanofi aventis.

Jeff Joseph, D.O. – Grant support from Medtronic MiniMed, LifeScan; Consultant for St. Jude Medical.

Diane Karl, M.D. – Grant Support from Amylin, sanofi-aventis; Consultant for Amylin, Novo Nordisk, sanofi aventis.

David Klonoff, M.D. – Grant support from Amylin, Eli Lilly, MannKind, Novo Nordisk and sanofi aventis.

Lori Laffel, M.D., MPH – Grant support from Abbott Diabetes Care, LifeScan; Consultant for Lilly, Medtronic, Novo Nordisk.

Charles Raine, III, M.D. – Consultant for Medtronic MiniMed; Speaker for Medtronic.

Virginia Tobiason, R.N. – Employee of Abbott.

Stuart Weinzimer, M.D. – Grant Support from Medtronic MiniMed.

Steven Wittlin, M.D. – Grant support from Novo Nordisk, sanofi aventis, Eli Lilly, Tomen; Consultant for Novo Nordisk, Medtronic MiniMed; Speaker for Novo Nordisk, sanofi aventis, Medtronic MiniMed.

Howard Wolpert, M.D. – Grant support from Medtronic MiniMed; Consultant for Abbott Diabetes Care.

Benefits and Limitations of Intermittent Blood Glucose, A1c, and Ketone Testing

David Klonoff, M.D., FACP
Mills-Peninsula Health Services, San Mateo, California, and UC San Francisco

Self monitoring of blood glucose (SMBG) is intended to: 1) educate patients about diet and exercise effects on glycemia; 2) protect patients by allowing immediate confirmation of hypoglycemia or hyperglycemia; 3) permit medication dosage adjustments; 4) identify factors that may raise blood glucose levels; and 5) motivate healthy behavior. SMBG has been clearly demonstrated to improve control in patients with T1DM and insulin-treated T2DM. The evidence for the benefit of SMBG in non-insulin-treated T2DM is less clear, but nevertheless the majority of studies and meta-analyses of this intervention have demonstrated benefit. The reasons why SMBG, in T2DM patients not using insulin, has failed to demonstrate improved control in some studies include: 1) too little feedback about results by healthcare providers; 2) poor self-care skills by patients in order to be able to adjust treatment; 3) a lack of consensus within the diabetes professional community as to the optimal frequency and timing of SMBG; 4) a dearth of postprandial data which would likely yield surprisingly (to the patient) high postprandial blood glucose levels and provide greater insight into glycemic fluctuations; 5) the cost of disposables limits testing; and 6) the pain and inconvenience of testing limits testing. Methodologic flaws in some studies of the effects of SMBG have also undermined the appeal of this monitoring approach in non-insulin users with T2DM. SMBG is increasingly being recognized as a part of intensive therapy for all forms of diabetes. As consensus standards for testing, as well as improved monitors, are continually developed, then the amount of SMBG performed in all types of diabetes is expected to increase.

Benefits and Limitations of Intermittent Blood Glucose, A1c, and Ketone Testing

Lori Laffel, M.D., M.P.H.
Joslin Diabetes Center, Harvard University, Boston, Massachusetts

Glycemic control is an important determinant of both short and long-term health for persons with diabetes. Frequency of blood glucose monitoring is critically linked to glycemic control as measured by A1c. None-the-less, frequent blood glucose monitoring is challenging for many patients with diabetes due to pain, cost, fear, and burden. New technologies can assist with overcoming many of these burdens and improve the ease with which blood glucose can be measured. Interpretation of blood glucose becomes critical in order to modify diabetes treatment including medications, activities, and food intake.

A1c remains the “gold standard” for predicting complications based on the findings of the DCCT and UKPDS. Knowledge of A1c results by health care providers has been linked to improved glycemic control. A1c provided at the point of care has also been linked to initial improvements in control but additional studies are needed to demonstrate the ability of point of care A1c testing to sustain long-term improvements in glycemic outcomes.

Finally, self blood ketone testing has recently become possible. The opportunity to measure blood beta hydroxybuterate provides an opportunity to intervene early for rising blood sugars and impending ketosis in order to prevent further deterioration and need for costly emergency room assessment and/or hospitalization. Limitations of blood ketone testing result from lack of experience by providers and patients with need for additional education and experience regarding this new technology to allow for wider dissemination.

The Current Environment of CGM Technologies

Barry Ginsberg, M.D., Ph.D.
Becton, Dickinson and Company, Franklin Lakes, New Jersey

Over the next year or two, continuous glucose monitoring will become more popular, but the ultimate success of the technology depends on developing appropriate clinical schemata for use. Continuous monitoring brings new forms of data to clinical care, such as glucose vectors (direction and speed of change of blood glucose), frequent inter-meal sampling and hypoglycemia prediction. In this period, we will discuss the basics of the technologies, strengths and weaknesses and potential methods to clinically exploit this data for optimal diabetes care.

HbA1C, Glycemic Variability (Stability) and Other Outcome Markers – What is the Most Telling?

Lawrence Blonde, M.D., FACP
Ochsner Clinic Foundation, New Orleans, Louisiana

Diabetes is the #1 cause of adult blindness, non traumatic amputation and end stage kidney disease in the US.[CDC fact sheet, p 7] Largely due to chronic complications, diabetes exacts great personal and societal costs. An American Diabetes Association study estimated that in 2002 the combined direct and indirect costs of diabetes in the US totaled $132 billion.

A1C provides a measure of mean plasma glycemia over the past 2 to 3 months and is an accepted surrogate for the development of complications. However, the A1C provides no information about glycemic variability. Knowledge of glucose patterns is required to adjust therapy to achieve A1C goals. Moreover, glycemic peaks and glycemic variability may be associated with adverse patient outcomes over and above their contribution to the A1C. This presentation will review relationships between A1C, glycemic variability and patient outcomes.

Using CGM in Diagnosing and Managing Hypoglycemia Unawareness – Discussion and Demonstation

Howard Wolpert, M.D.
Joslin Diabetes Center, Boston, Massachusetts

Intensive diabetes therapy is complicated by an increased rate of hypoglycemia and the development of hypoglycemia unawareness. The talk will focus on the potential role of 'real-time' CGM in preventing hypoglycemia, and in overcoming this barrier to the implementation of intensive therapy. Issues to be discussed will include the differences between capillary blood and interstitial glucose levels, the impact of lag times on sensor calibration and accuracy, and the importance of patient education to minimize the risk for hypoglycemia from uncontrolled post-prandial bolusing.

Impact of Real Time Continuous Readings on Children and Their Families

Darrell Wilson, M.D.
Stanford University, Palo Alto, California

Real-time continuous glucose sensors have great potential to improve glycemic management in children and adolescents with diabetes and other disorders of glucose regulation. Many questions remain, however, about how to best use these devices to maximize benefit while avoiding adverse impacts. Issues such as patient selection as well as the ideal frequency and duration of sensor wear remain unresolved. The best methods to translate glucose data into a meaningful acute adjustments in therapy as changes in basal insulin therapy are being developed and studied. Optimization of algorithms to detect significant hypoglycemia, particular at night, with acceptable sensitivity and sufficiently low false positive rates continues to be important process.

Algorithms for Care in Adults Using CGM

Irl Hirsch, M.D.
University of Washington, Seattle, Washington

Several issues will become clear immediately after CGM is introduced. First, one cannot utilize this tool effectively without a good understanding of insulin therapy. Next, instead of considering blood glucose readings only as a stagnant number, we will need to develop algorithms on how to best think of "glycemic trending". These algorithms will vary based on insulin dose, type of food recently eaten, insulin-on-board, and exercise. The challenge will be to make these simple so the majority of patients can use this new technology.

What Will it Take to Get CGM Reimbursed – Examining Compelling Factors

Claudia Graham, Ph.D.
Medtronic MiniMed, Northridge, California

This presentation will focus on the current reimbursement environment for existing diabetes technologies, as well as expectations for reimbursement of emerging technologies. Participants will learn methods for effectively coding, and techniques for improving reimbursement with third party payors will be discussed. Ongoing reimbursement activities by professional societies will be highlighted, with examples of how clinicians can become more active in future reimbursement and coverage.

Physiological Monitoring of the Warfighter

Colonel Karl Friedl, Ph.D.
Commander, United States Army Institute of Environmental Medicine, Natick, Massachusetts

The Army has sophisticated prognostic and diagnostic systems for vehicles and weapons systems but only subjective intelligence on its own human forces. Army biomedical researchers have developed a reliable non-invasive monitoring prototype system for heat strain, dehydration, mental fatigue, and incapacitation. When they become available, glucose and lactate sensors will help define normal metabolic physiology in extreme environments, and provide a basis for soldier metabolic monitoring and early triage following injury, hypoglycemia associations with behavioral deficits, and energy deficits in intense exertion. This research has dual use applications to remote monitoring of children with diabetes on the playground.

Treatment Goals and Strategies for Type 2 Diabetes – The Changing Landscape

Chan Cooppan, M.D.
Joslin Diabetes Center, Harvard University, Boston, Massachusetts

While glycemic control is very important for microvascular complications we are no longer glucocentric. To reduce the risk of cardiovascular disease the comorbid risk factors, obesity, hypertension, dyslipidemia and the prothrombotic state need to be treated aggressively. Outcome studies support the glycemic, blood pressure and lipid goals.

Exciting new therapies for glycemic control such as the amylin analog, Symlin® and the GLP-1 like compound-exenatide are available. Soon DPP4-inhibitors, inhaled insulin and rimonabant- an agonist for the CB1 receptor of the endocannabinoid system will also be available.

In-Hospital Management of Hyperglycemia - What is the Evidence?

Michael Bryer-Ash, M.D., FRCP
UCLA, Los Angeles, California

Since the publication of the AACE/ACE consensus statement on the management of in-patient hyperglycemia in December 2003, considerable attention has focused on the feasibility of attaining the glycemia targets and on analysis of recent intervention trials in various target groups. This presentation provides a critical review of the major clinical trials and other outcomes data and discusses their implications for implementation of programs to manage the high percentage of acutely ill hospitalized patients who manifest hyperglycemia.

Algorithms for Intensive Insulin Therapy of Diabetes in the Hospital - In the ICU and the Wards

Stephen Clement, M.D.
Georgetown University, Washington, DC

Tightly controlling glucose levels in patients with diabetes/hyperglycemia in the hospital setting has been shown to reduce mortality and morbidity. The American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) have published targets of glucose control that are much lower than is presently achieved in most hospitalized patients. In order to achieve these strict targets, sophisticated methods for giving insulin are required. Many hospitals, including our own, have developed standardized order sets to facilitate implementing these methods. The lecture will detail the algorithms and systems required to implement strict glycemic control in the hospitalized patient.

Algorithms for Intensive Insulin Therapy of Diabetes in the Hospital - In the ICU and the Wards

Jeffrey Joseph, D.O.
Thomas Jefferson University, Philadelphia, Pennsylvania

Hyperglycemia is common in patients admitted to the hospital on the morning of surgery. Primary care physicians, surgeons, and anesthesiologist rarely educate people with diabetes to SMBG more frequently and adjust insulin dosages more aggressively to achieve near-normal BG control prior to hospital admission. Bowel cleansing, prolonged fasting, withdrawal of oral hypoglycemia medication, and mental/physical stress make pre-operative control of BG difficult.

Prospective clinical trials are needed to determine whether aggressive treatment of hyperglycemia, diagnosed at the time of hospital admission, has a positive, negative, or neutral effect on outcome for a specific patient population. Many anesthesiologists and surgeons proceed to the OR despite pre-operative BG levels above 250 mg/dl, choosing to correct hyperglycemia during anesthesia and surgery. Other physicians choose to delay surgery for 6 to 24 hours to achieve BG control and to correct intravascular volume and electrolyte abnormalities. Acute correction of hyperglycemia can lead to hypokalemia and dehydration leading to hypotension/hypo-perfusion with the induction of anesthesia. Our laboratory is currently studying whether persistent hyperglycemia and glycosuria are risk factors for developing deep vein thrombosis.

Although the need for frequent BG measurements seems obvious to detect and manage hyperglycemia, studies have shown a low frequency of BG monitoring before, during, and after surgery. Frequent BG monitoring remains the key to safe and effective insulin delivery. Insulin is delivered most commonly in the OR by bolus intravenous injection of 4 to 10 units. Large bolus doses of IV insulin can saturate the peripheral insulin receptor pool and prolong insulin's BG lowering effect. The continuous intravenous infusion of regular insulin at low rates of delivery (1 to 6 units/hour) provides satisfactory BG control and a greater ability to decrease plasma levels acutely.

Patients that develop hypoglycemia in the hospital are at increased risk for adverse cardiovascular events and death. The degree/duration of hypoglycemia and the patient populations at greatest risk for increased morbidity/mortality remains unknown. Anesthetics, analgesics, and cardiovascular medications may attenuate the hypertension, cardiac arrhythmias, and myocardial ischemia secondary to increased plasma epinephrine levels and increased sympathetic tone, as BG levels fall below 70 mg/dl.

Anesthesiologists tend to avoid glucose-containing intravenous solutions due to the low incidence of intra-operative hypoglycemia, the high incidence of insulin resistance (leading to stress hyperglycemia), and research data that suggests an exogenous source of carbohydrate does not prevent protein catabolism. This management leads to low post-operative hepatic glycogen stores, and may increase the risk for hypoglycemia. This risk is decreased by providing an exogenous source of glucose (5 to 10 gm/hour) in the immediate post-operative period. Intravenous glucose should be used to treat post-operative hypoglycemia, rather that an IM or IV dose of glucagon.

Once approved by the FDA, continuous glucose sensors (CGS) will become the standard of care for all patients undergoing major surgery. Clinical trials are currently underway in surgical patients to determine whether interstitial fluid glucose sensors have sufficient point, direction, and rate of change accuracy to direct insulin therapy and detect hypoglycemia with a high degree of sensitivity and specificity. Other glucose sensor technologies measure glucose within the bloodstream or automatically deliver a sample of patient blood to an external sensor. Robust CGS devices will facilitate more aggressive titration of subcutaneous and intravenous insulin delivery and eliminate the fear of hypoglycemia.

Eliminating Sliding Scale Insulin in the Hospital

David Baldwin, Jr., M.D.
Rush University, Chicago, Illinois

In 2002 we began a program of house staff reeducation aimed at teaching our residents how to manage inpatient hyperglycemia using basal/bolus insulin protocols. After all medicine PGY-1's had received training, we set a policy that SSRI was no longer permitted on any medical unit. Each medical PGY-1 receives ~10 hours of ward-based instruction in insulin management by an attending endocrinologist. In July 2005, we extended the reach of the cultural change to include all other services. All resident training in our hospital now takes place in the new basal/bolus insulin culture. This represents an achievable goal for all academic medical centers.

Inhaled Insulin – An Update and A Look Forward

William Cefalu, M.D.
Louisiana State University, Baton Rouge, Louisiana

A major limitation for advancing to intensive insulin therapy in subjects with diabetes is that the only viable way to administer insulin is through injection. Delivery options that use dermal, nasal and oral approaches have been explored. The oral approach may include gastrointestinal, buccal or pulmonary uptake. Recent evidence shows that delivery of insulin via the oral cavity with uptake occurring in the pulmonary alveoli may be the most viable clinical option in the future.

Therapeutics of Pramlintide (Symlin®) in Type I Diabetes

Diane Karl, M.D.
The Endocrine Clinic, Portland, Oregon

Pramlintide, an analog of the naturally occurring hormone amylin, is a new therapeutic agent in the treatment of type 1 (and insulin-treated type 2) diabetes. Amylin is co-secreted with insulin by the beta cell and is absent in people with type 1 diabetes. Pramlintide is administered before meals in conjunction with prandial insulin and helps control postprandial glucose increments by slowing gastric emptying, suppressing (inappropriately elevated) glucagon and decreasing caloric intake. The strategies of reducing mealtime insulin at initiation and starting with a low dose which is gradually titrated up improve safety and tolerability.

Exenatide (Byetta®) and Other Incretin Mimetic Therapies – A Look at Changing Treatment Paradigms

John Buse, M.D., Ph.D., CDE, FACE
University of North Carolina, Chapel Hill, North Carolina

Considerable research has focused on the multiple effects of incretins, intestinal hormones that promote insulin secretion coupled to food ingestion. Glucagon-like peptide-1 (GLP-1) is the most active incretin in man. GLP-1 exerts its antihyperglycemic effects through multiple mechanisms: stimulating glucose-dependent insulin release, reducing excess glucagon secretion, slowing gastric emptying, improving satiety, promoting weight loss and stimulating differentiation and proliferation of beta-cells. These issues will be discussed focusing on the clinical utility of the new antidiabetic agent, exenatide.

Technology Update – Insulin Pens, Smart Pumps, Disposable Pumps, and Data Mangement

Suzanne Ghiloni, R.N.
Joslin Diabetes Center, Harvard University, Boston, Massachusetts

Few diseases demand the self-care that diabetes does. For this reason, updated technology- new devices and software enhancements- are important adjuncts in the diabetes management toolbox. This presentation will discuss some of the available products that can improve patient's self-care and assist with glucose control. Treatment approaches and challenges will be reviewed, highlighting candidate selection and general considerations and applications of these products. Through case presentations this session will include several software programs, utilizing reports that can assist both patient and provider in viewing trends and patterns in glucose management.

Discussion of Current and Future Trends in Diabetes Technology

Moderator - Stuart Weinzimer, M.D.
Yale University, New Haven, Connecticut

As continuous glucose monitoring devices become available, we must learn how to utilize this new technology for routine diabetes management. There are currently no standard algorithms or guidelines for the use of real-time glucose monitoring devices in clinical practice. The objectives of this presentation are to illustrate the complexities of diabetes management in the age of real-time continuous glucose monitoring and provide a conceptual framework for using real-time monitors in the real world.

CALL FOR ABSTRACTS

Sixth Annual

DIABETES TECHNOLOGY MEETING

Applying science and engineering to fight diabetes

November 2 - 4, 2006
Westin Peachtree Plaza Hotel, Atlanta, Georgia

Presented by DIABETES TECHNOLOGY SOCIETY
www.diabetestechnology.org

PRE-MEETING WORKSHOPS

- **Reimbursement Strategies for Diabetes Technologies**
  The payor's perspective
- **Interstitial Fluid Physiology and Glucose Sensors**
  What are we really measuring?
- **Information Technology Applied to Diabetes**
  An emerging tool to improve patient outcome

MEETING TOPICS

- **Technologies for Metabolic Monitoring**
  New methods for measuring glucose and markers of glycemic control
- **Mathematical Formulas for Expressing Continuously Monitored Glucose Data**
  Quantifying temporal variability
- **Artificial Pancreas**
  Including automatic glucose sensors, insulin delivery systems and feedback control
- **Inhalation and Other Iternate Routes for Insulin Delivery**
  Avoidance of painful needle injections
- **MEMS (Micro-Electro-Mechanical Systems)**
  Measuring glucose and delivering insulin on the millimeter scale
- **Computers and Diabetes**
  Including case management, telemedicine, educational tools, metabolic modeling, software, and hardware

PROGRAM HIGHLIGHTS

- **Two Poster Sessions**
  Posters will be presented in two groups during evening receptions on November 2 and November 3, 2006
- **Inventors and Their Inventions**
  Inventors demonstrating actual models of their own technology, products, or software
- **Annual Diabetes Technology Survey**
  Results will be presented and discussed in real-time

For more information

Diabetes Technology Society
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Phone: 800-397-7755 or 650-357-7140 Fax: 650-349-6497
e-mail: info@diabetestechnology.org
website: www.diabetestechnology.org

ABSTRACT SUBMISSION

- Deadline to submit: June 30, 2006
- For information on how to submit an Abstract go to: www.diabetestechnology.org
- Abstracts will be published in the *Journal of Diabetes Technology,* distributed to all Meeting attendees, and considered for oral and poster presentation.

PETERSON STUDENT RESEARCH AWARDS

- **Gold $1000 / Silver $500 / Bronze $300**
- Also includes travel, lodging, and registration for best 3 Diabetes Technology Abstracts first-authored by students

IN COOPERATION WITH

- Centers for Disease Control and Prevention
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- UC Berkeley Department of Bioengineering
- Georgia Tech/Emory Center for the Engineering of Living Tissues
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Journal of Diabetes Technology

A new bimonthly peer-reviewed scientific journal

The JDT Editorial Board consists of leading international scientists and clinicians in the fields of diabetes technology.

JDT will cover all aspects of diabetes technology including: glucose monitoring; insulin and metabolic peptide delivery; the artificial and bioartificial pancreas, telemedicine; software for modeling; physiologic monitoring; diagnostic tests of glycation; and the use of bioengineered tools such as MEMS, new biomaterials, and nanotechnology to develop new sensors and actuators to be applied to diabetes.

The journal will include the following sections:

Original Articles

Review Articles

Commentaries

Diabetes and the Internet

Diabetes Neurological and Microvascular Technology

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The journal will also include the following regular columns:

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A non-profit organization committed to applying science and technology in the fight against diabetes

Eliminating Sliding Scale Insulin in the Hospital

Submitted By David Baldwin, Jr., M.D.
Rush University Medical Center, Chicago, Illinois

Rush Inpatient Adult Diabetes Management Guidelines – June 2005

Initial Assessment of the Hyperglycemic Patient

Preexisting Diabetes

- What types of insulin or oral agents?
- What are the doses and the dose timing?
- What have the blood glucoses been at home?
- When was diabetic therapy last taken?

New Onset Hyperglycemia

- Is it TYPE 1 or TYPE 2?
- Younger age and ketones favor TYPE 1
- Older age, FH of DM, overweight suggest TYPE 2
- Is there a provocation: infection or other stress?
- Is there glucocorticoid Rx?
- Is there hyper-alimentation?

INITIAL EVALUATION

- Check HBA1C on all patients with hyperglycemia

ALWAYS MUST CONSIDER AND R/O DKA

- Nausea and vomiting are important clues for DKA
- 10% of DKA's have glucose < 300
- Check electrolytes and serum acetone if HCO3<18
- Acetone may initially be negative in DKA
- If DKA is a possibility check an ABG
- Check BUN/Cr. Check U/A to look for proteinuria
- Best test for proteinuria is urine microalbumin
- Clinical estimation of left ventricular function is important when assessing the suitability of metformin or a glitazone
- What is the IV fluid? Is the patient eating?
- How insulin resistant is the patient i.e. How much overweight?

PREPARED BY THE SECTION OF ENDOCRINOLOGY
THIRD EDITION

INITIAL APPROACH TO INPATIENT HYPERGLYCEMIA

- Check HBA1C and begin QID glucoses by fingerstick.
- Patients who were treated with oral anti-diabetic agents prior to admission should be placed on basal insulin if they are NPO (e.g. post-op), or if glucose is > 160 mg/dl. It is best to avoid sulfonylureas in NPO patients, metformin in severely ill patients or patients with elevated serum creatinine, and glitazones in patients with heart failure. In general, most inpatients with blood glucoses greater than 140-160 mg/dl should be started on insulin therapy, and have oral agents discontinued.
- HBA1C >7% represents suboptimal diabetic control, and anti-diabetic Rx should be improved prior to discharge.
- In general each oral anti-diabetic agent can only lower HBA1C by 1-2%.
- Thus a pt. with HBA1C of 12% on 2 oral agents will require insulin in order to lower HBA1C < 7%.
- There are potentially 3 types of SQ insulin which will need to be ordered: **basal, prandial, and correction**.

Cont. Eliminating Sliding Scale Insulin in the Hospital

BASAL INSULIN GUIDELINES

- All patients receiving insulin must first have an order for basal insulin. Basal insulin is required to meet the fasting needs of the patient. Basal insulin represents 100% of the total daily insulin needs in NPO patients, and ~ 50% of the total daily insulin needs in patients who are eating. Patients who are eating will also need prandial insulin to accompany meals and all patients may also receive supplementary correction doses. **Patients must have basal insulin even if NPO to avoid developing diabetic ketoacidosis and/or toxic hyperglycemia.**
- First, select a basal. The 2 choices are once daily glargine insulin, or twice daily NPH insulin.
- If a patient is new to insulin and NPO: start with glargine insulin 0.3 units per kg. SQ every 24 hours. Glargine (Lantus) may be given daily at 8 AM or 6 PM. This is recommended for all post-op patients, except ICU patients who are treated with an IV insulin infusion.
- If a patient is new to insulin and eating: start with NPH 0.2 units/kg. Q 8 AM and 0.1 units/kg. Q 6 PM.
- If a patient is admitted and already taking glargine insulin, initially continue the same daily dose at either 8 AM or 6 PM whether NPO or eating.
- If a patient is admitted already taking NPH insulin, initially continue the same doses if eating. If NPO reduce the AM dose by 50% and continue the same PM dose.
- If a patient is currently treated with 70/30 or 75/25 insulin: continue 70% of these total doses as NPH insulin.
- If a patient is currently treated with Lente insulin, substitute unit per unit with NPH.
- Revise glargine insulin dose daily if 6 AM blood glucose is less than 80 mg/dl or more than 120 mg/dl.
- Revise AM NPH insulin dose if 6 PM glucose is less than 100 or more than 180 mg/dl.
- Revise PM NPH dose if 6 AM glucose is less than 80 or more than 120 mg/dl.
- To change BID NPH to once daily glargine give 80% of the total daily dose of NPH as glargine QHS.
- **Glargine may not be mixed with other insulins;** all other insulins are mixable.

HYPERALIMENTATION

Hyperglycemic patients who are placed on continuous **tube feeds** should receive equal doses of NPH at 8 AM and 8 PM. Insulin doses should be revised daily based on QID blood glucose tests. **Remember to begin 10% dextrose (D10W) IV fluid immediately if tube feeds are ever interrupted in patients receiving insulin. Use the same rate as the tube feeds.**

Hyperglycemic patients on **CVN** should have regular insulin added to the CVN bag each day as well as receiving NPH insulin SQ Q12 hours until the CVN has enough insulin.

HIGH DOSE GLUCOCORTICOIDS

Cont. Eliminating Sliding Scale Insulin in the Hospital

Steroid therapy may create new hyperglycemia and will worsen preexisting hyperglycemia.

Oral agents are ineffective and NPH +/- aspart insulin is usually required BID, often at high doses.

Unlike methylprednisolone and dexamethasone, prednisone given QAM only lasts ~20 hours and PM dosing of NPH requires reduction to avoid AM hypoglycemia.

PRANDIAL INSULIN GUIDELINES

- Prandial insulin is rapid acting insulin which specifically accompanies meals when patients are eating.
- Aspart insulin (Novolog) is always preferred to Regular insulin due to aspart's more rapid onset (15 min), peak (60 min) and shorter duration (3 hours).
- Aspart insulin is given with meals at 8 AM and 6 PM to patients on NPH basal insulin
- Aspart insulin is given with meals at 8 AM, 1 PM and 6 PM to patients on glargine basal.
- If a patient is admitted already taking lispro or Regular insulin, substitute unit per unit with aspart insulin.
- If a patient is admitted already taking prandial insulin and is eating, initially continue the same doses.
- If a patient is admitted already taking 70/30 or 75/25 insulin, first convert ea. total dose to 70% NPH and 30% aspart. Give the 30% aspart doses at 8 AM and 6 PM.
- **If a patient is new to insulin and eating start with: 0.1 unit per kg aspart insulin with meals at 8 AM, 1 PM, and 6 PM if receiving glargine basal, or at 8 AM and 6 PM if receiving NPH basal insulin.**
- Revise prandial insulin doses daily if pre-lunch, pre-dinner or bedtime blood glucose levels are out of the target range 110-180 mg/dl.

CORRECTION DOSE GUIDELINES

- Further downward adjustment of elevated blood glucose is achieved through the use of correction doses of aspart insulin, which may be given QID as needed. These function as a third layer of insulin supplementing the basal and prandial insulin doses.
- Correction doses are recommended for any blood glucoses greater than 140 mg/dl. Construct scales to begin at a glucose of 140 mg/dl and to increase by 40 mg/dl per glucose level. Each mealtime and HS gets its own scale.
- Begin to build the correction scales with an aspart dose equal to 10% of the initial total daily insulin dose and increase by 5-10% more per glucose level.
- If a patient is NPO, the scales for each of the four times per day can be the same.
- If a patient is eating, the scale for bedtime should be half as much insulin as a mealtime scale.
- Correction scales should be modified periodically.

Algorithms for Intensive Insulin Therapy of Diabetes in the Hospital - In the ICU and the Wards

Georgetown University Hospital, Washington, DC
Submitted by Stephen Clement, M.D.

Georgetown University Hospital
MedStar Health

ADULT INSULIN INFUSION ORDER FORM (Not for DKA)

☐ STAT

PATIENT IDENTIFICATION

Allergy: _____

Check Box that Applies

Goal BG = _____ (Usually 80 - 120 mg / dL)

See Back for General Guidelines

I. **STANDARD DRIP:** Regular insulin 100 Units / 100 ml 0.9% NaCl via an infusion device.

II. **INITIATING THE INFUSION:**

- ☐ **Bolus Dose:** Regular insulin 0.1 Unit / kg = _____ Units
- ☐ **Algorithm 1:** Start here for most patients.
- ☐ **Algorithm 2:** Start here if s/p CABG, s/p solid organ transplant or islet cell transplant, receiving glucocorticoids, or patient with diabetes receiving > 80 Units / day of insulin as an outpatient.

Algorithm 1		**Algorithm 2**		**Algorithm 3**		**Algorithm 4**	
BG	Units / hr	BG	Units / hr	BG	Units / hr	BG	Units / hr
< 60 = Hypoglycemia (See below for treatment)							
< 70	Off	< 70	Off	< 70	Off	< 70	Off
70 - 109	0.2	70 - 109	0.5	70 - 109	1	70 - 109	1.5
110 - 119	0.5	110 - 119	1	110 - 119	2	110 - 119	3
120 - 149	1	120 - 149	1.5	120 - 149	3	120 - 149	5
150 - 179	1.5	150 - 179	2	150 - 179	4	150 - 179	7
180 - 209	2	180 - 209	3	180 - 209	5	180 - 209	9
210 - 239	2	210 - 239	4	210 - 239	6	210 - 239	12
240 - 269	3	240 - 269	5	240 - 269	8	240 - 269	16
270 - 299	3	270 - 299	6	270 - 299	10	270 - 299	20
300 - 329	4	300 - 329	7	300 - 329	12	300 - 329	24
330 - 359	4	330 - 359	8	330 - 359	14	> 330	28
> 360	6	> 360	12	> 360	16		

III. **MOVING FROM ALGORITHM TO ALGORITHM:**

- Moving Up: An algorithm failure is defined as blood glucose outside the goal range x 2 hours (see above goal), and the blood glucose does not change by at least 60 mg / dL within 1 hour.
- Moving Down: When blood glucose is < 70 mg / dL X 2 ***OR*** if BG decreases by greater than 100 mg / dL in an hour
- Patients not controlled with the above algorithms need an endocrine consult.
- Notify MD before changing Algorithms.

IV. **Decrease infusion by 50% if nutrition (tube feeds or TPN) is discontinued or significantly reduced. Reinstitute hourly BG checks x 4 hours.**

V. If meals started, write separate order for pre-meal novolog (4 - 6 units qac). Do not advance to higher algorithm during 2 hour post prandial period.

VI. **PATIENT MONITORING:**

- Check capillary BG every hour until it is within goal range for 4 hours, then decrease to every 2 hours for 4 hrs, and if rema ins at goal may decrease to every 4 hours.

VII. **TREATMENT OF HYPOGLYCEMIA (BG < 60 mg / dL)**

- Discontinue insulin drip AND
- Give $D_{50}W$ IV
  - ❖ Patient conscious: 25 ml (1/2 amp)
  - ❖ Patient unconscious: 50 ml (1 amp)
- Recheck BG every 20 minutes and repeat 25 ml of $D_{50}W$ IV if < 60 mg / dL. Restart drip once blood glucose is > 70 mg / dl x 2 checks. Restart drip with lower algorithm (see moving down)

VIII. NOTIFY THE PHYSICIAN:

- For any blood glucose change greater than 100 mg / dL in one hour.
- For blood glucose > 360 mg / dL
- For hypoglycemia which has not resolved within 20 min. of administering 50 ml of $D_{50}W$ IV and discontinuing the insulin drip.

Prescriber's Signature _____ Pager # _____ Date _____

TMR 170.334 (7/11/05) (F3F)

GENERAL GUIDELINES

- Surgical patients who have received an oral diabetes medication within 24 hours should start when BG > 120 mg / dL. All other patients can start when BG ≥ 70
- Insulin infusions should be discontinued when a patient is eating AND has received 1st dose of subcutaneous insulin.

INTRAVENOUS FLUIDS:

- Most patients will need 5 - 10 GM of glucose per hour D_5W or D_5 / 0.45% NS at 100 - 200 ml / hr or equivalent (TPN, enteral feeds, etc.)

INITIATING THE INFUSION:

- **Algorithm 3:** For patients not controlled on Algorithm 2. NO PATIENTS START HERE without authorization from the endocrine service.
- **Algorithm 4:** For patients not controlled on Algorithm 3. NO PATIENTS START HERE.

Georgetown University Hospital
MedStar Health

ADULT INSULIN INFUSION FLOWSHEET (Not for DKA)

Allergies: _____

Goal capillary blood glucose (BG) = _____ (usually 80 - 180 mg / dl)

❑ Regular insulin bolus _____ Units given at _____ _____
Date / Time Initial

❑ No bolus

❑ Regular Insulin (100 Units / 100 ml 0.9% NaCl) drip started at _____ Units / hr, using Algorithm _____

Date / Time _____ Initials _____

4. Insulin drip adjustments are made per the algorithms below. Notify physician before changing from current algorithm.

   Moving Up: An algorithm failure is defined as a capillary BG outside the goal range and the BG does not change by at least 60 mg / dL within one hour.

5. **Moving Down:** When FB is < 70 mg / dl X 2 capillary BG checks, or if BG decreases by greater than 100 mg / dL in an hour.

6. **Decrease infusion by 50% if nutrition (tube feeds or TPN) is discontinued or significantly reduced. Reinstitute hourly BG check x 4 hours.**

7. If meals started, write separate order for pre-meal novolog (4 - 6 units qac). Do not advance to higher algorithm during 2 hour post prandial period.

8. Patient monitoring:
   - Check capillary BG every hour until it is within goal range for 4 hours, then decrease to every 2 hours for 4 hours, and if remains at goal may decrease to every 4 hours.

9. **TREATMENT OF HYPOGLYCEMIA BG < 60 mg / dL**
   - Discontinue insulin drip AND
   - Give $D_{50}W$ IV
     - ❖ Patient conscious: 25 ml (1/2 amp)
     - ❖ Patient unconscious: 50 ml (1 amp)
   - Recheck BG every 20 minutes and repeat 25 ml of $D_{50}W$ IV if < 60 mg / dL. Restart drip once blood glucose is > 70 mg / dl x 2 checks. Restart drip with lower algorithm (see moving down)

Algorithm 1		Algorithm 2		Algorithm 3		Algorithm 4	
BG	Units / hr	BG	Units / hr	BG	Units / hr	BG	Units / hr
< 60 = Hypoglycemia (See above for treatment)							
< 70	Off	< 70	Off	< 70	Off	< 70	Off
70 - 109	0.2	70 - 109	0.5	70 - 109	1	70 - 109	1.5
110 - 119	0.5	110 - 119	1	110 - 119	2	110 - 119	3
120 - 149	1	120 - 149	1.5	120 - 149	3	120 - 149	5
150 - 179	1.5	150 - 179	2	150 - 179	4	150 - 179	7
180 - 209	2	180 - 209	3	180 - 209	5	180 - 209	9
210 - 239	2	210 - 239	4	210 - 239	6	210 - 239	12
240 - 269	3	240 - 269	5	240 - 269	8	240 - 269	16
270 - 299	3	270 - 299	6	270 - 299	10	270 - 299	20
300 - 329	4	300 - 329	7	300 - 329	12	300 - 329	24
330 - 359	4	330 - 359	8	330 - 359	14	> 330	28
> 360	6	> 360	12	> 360	16		

Rate Changes are to be verified by another nurse, pharmacist or physician.

Date / Time	Lab BG	FSBG	Algorithm #	Reg Insulin IV		Comments	Initials
				Bolus	Rate Units / hr		
							/
							/
							/
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							/

TMR 141.003 (7/14/05) (F3F)

Date / Time	Lab BG	FSBG	Algorithm #	Reg Insulin IV		Comments	Initials
				Bolus	Rate Units / hr		
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Georgetown University Hospital

MedStar Health

ADULT SUBCUTANEOUS INSULIN ORDER FORM

☐ STAT

PATIENT IDENTIFICATION

Check Appropriate Boxes that Apply and Carry Out All Orders Unless Crossed Out.

Date: _____ **Allergy:** _____

Diet: ☐ Low Consistent Carbohydrate (1200 - 1600 cal) ☐ Medium Consistent Carbohydrate (1800 - 2000 cal)
☐ High Consistent Carbohydrate (2200 - 2400 cal)

Finger Stick Glucose: (FSBG)

☐ q 4 hrs (for ICU patients or on tube feeds) ☐ q ac, hs (for patients tolerating po well)
☐ q 6 hrs (for ICU or on tube feedings) ☐ Call HO for FSBG ≤ 50 or > 350

Goal Premeal BG = _____ (Rec 80 - 120)

SCHEDULED INSULIN

	Breakfast	Lunch	Dinner	Bedtime
Basal Insulin Orders	Give _____ units of: ☐ NPH ☐ Glargine (Lantus®)			Give _____ units of: ☐ NPH ☐ Glargine (Lantus®)
***Prandial Insulin Orders**	Give _____ units of: ☐ Aspart (Novolog®)	Give _____ units of: ☐ Aspart (Novolog®)	Give _____ units of: ☐ Aspart (Novolog®)	
Mixed Insulin (not preferred)	Give _____ units of: Novolog Mix 70/30		Give _____ units of: Novolog Mix 70/30	
Tube-Feeding (TF)	Continuous	Give _____ units of: ☐ Novolog ☐ Regular		every 6 hours
	Bolus	Give _____ units of: ☐ Novolog ☐ Regular		with each Tube Feed Bolus.

SUPPLEMENTAL INSULIN

☐ **Low Dose Algorithm**
(For pts requiring ≤40 units of insulin / day)

FSBG	Additional Insulin
121 - 199	1 unit
200 - 249	2 units
250 - 299	3 units
300 - 349	4 units
> 349	5 units

Reduce HS DOSE by half

☐ **High Dose Algorithm**
(For pts requiring > 80 units of insulin / day)

FSBG	Additional Insulin
121 - 199	2 units
200 - 249	4 units
250 - 299	7 units
300 - 349	10 units
> 349	12 units

Reduce HS DOSE by half

☐ **Medium Dose Algorithm**
(For pts requiring 40 - 80 units of insulin / day)

FSBG	Additional Insulin
121 - 199	1 unit
200 - 249	3 units
250 - 299	5 units
300 - 349	7 units
> 349	8 units

Reduce HS DOSE by half

☐ **Individualized Algorithm**

FSBG	Additional Insulin
121 - 199	
200 - 249	
250 - 299	
300 - 349	
> 349	

Reduce HS DOSE by half

☐ Aspart (Novolog®) is the preferred agent
☐ Regular Insulin - (Call Pharmacy for approval)

☐ **Customized Algorithm**

FSBG	Additional Insulin

Reduce HS DOSE by half

☐ Call HO for FSBG < 50 or > 350

PRE-OP NPO:

☐ Reduce nightime NPH or Lantus by 20% ☐ Reduce next morning NPH or Lantus by 50%

* Give insulin (before or after) meals. Reduce prandial dose based on percent of meal ingested. (i.e., if 50% of calories ingested, give 50% of dose).

For BG < 60 mg / dL

A. If patient can take PO, give 15 grams of fast acting carbohydrate
   - 4 oz. Apple or Orange juice (No added sugar and no other juices)
   - 4 oz. Soda (Not diet soda)
   - Sugar (Dissolve 3 packets in water)

   Repeat FSBG in 20 minutes. If FSBG is < or = 60 mg / dl, repeat juice, soda or sugar.
   When BG > 60 mg / dl, give snack or meal in ½ hour. Snack = 1 pkg Graham crackers and 8 oz. skim milk.

B. If patient cannot take PO, give 25 ml of D50 as IV push.
   Check FSBG q 15 minutes and repeat above if BG < 80.
   If patient is without IV access, give Glucagon 1 mg IM and insert IV.

Prescriber's Signature _____ **Pager #** _____ **Date** _____

TMR 170.356 (7/14/05) (F3F)

Georgetown University Hospital
MedStar Health

DIABETIC FLOWSHEET (Adult)

FOR PRE-MEAL SQ INSULIN

❑ Aspart (Novolog®) SQ ❑ Regular Insulin SQ

SCHEDULED INSULIN

	Breakfast	Lunch	Dinner	Bedtime
Basal Insulin Orders	Give _____ units of: ❑ NPH ❑ Glargine (Lantus®)			Give _____ units of: ❑ NPH ❑ Glargine (Lantus®)
Prandial* Insulin Orders	Give _____ units of: ❑ Aspart (Novolog®)	Give _____ units of: ❑ Aspart (Novolog®)	Give _____ units of: ❑ Aspart (Novolog®)	
Mixed Insulin (not preferred)	Give _____ units of: Novolog Mix 70/30		Give _____ units of: Novolog Mix 70/30	
Tube-Feeding (TF)	Continuous	Give _____ units of: ❑ Novolog ❑ Regular		every 6 hours
	Bolus	Give _____ units of: ❑ Novolog ❑ Regular		with each Tube Feed Bolus.

SUPPLEMENTAL INSULIN

❑ **Low Dose Algorithm**
(For pts requiring ≤40 units of insulin / day)

FSBG	Additional Insulin
121 - 199	1 unit
200 - 249	2 units
250 - 299	3 units
300 - 349	4 units
> 349	5 units

Reduce HS DOSE by half

❑ High Dose Algorithm
(For pts requiring > 80 units of insulin / day)

FSBG	Additional Insulin
121 - 199	2 units
200 - 249	4 units
250 - 299	7 units
300 - 349	10 units
> 349	12 units

Reduce HS DOSE by half

❑ **Medium Dose Algorithm**
(For pts requiring 40 - 80 units of insulin / day)

FSBG	Additional Insulin
121 - 199	1 unit
200 - 249	3 units
250 - 299	5 units
300 - 349	7 units
> 349	8 units

Reduce HS DOSE by half

❑ **Individualized Algorithm**

FSBG	Additional Insulin
121 - 199	
200 - 249	
250 - 299	
300 - 349	
> 349	

Reduce HS DOSE by half

❑ Aspart (Novolog®) is the preferred agent
❑ Regular Insulin - (Call Pharmacy for approval)

❑ **Customized Algorithm**

FSBG	Additional Insulin

Reduce HS DOSE by half

FSBG Times _____

❑ Call HO for FSBG < 50 or > 350

* Give insulin (before or after) meals. Reduce prandial dose based on percent of meal ingested. (i.e., if 50% of calories ingested, give 50% of dose).

PRE-OP NPO:

❑ Reduce nightime NPH or Lantus by 20%

❑ Reduce next morning NPH or Lantus by 50%

❑ **For BG < 60 mg / dL**

A. If patient can take PO, give 15 grams of fast acting carbohydrate
- 4 oz. Apple or Orange juice (No added sugar and no other juices)
- 4 oz. Soda (Not diet soda)
- Sugar (Dissolve 3 packets in water)

Repeat FSBG in 20 minutes. If FSBG is < or = 60 mg / dl, repeat juice, soda or sugar.
When BG > 60 mg / dl, give snack or meal in ½ hour. Snack = 1 pkg Graham crackers and 8 oz. skim milk.

B. If patient cannot take PO, give 25 ml of D50 as IV push.
Check FSBG q 15 minutes and repeat above if BG < 80.
If patient is without IV access, give Glucagon 1 mg IM and insert IV.

TMR 170.360 (7/14/05) (F3F)

Georgetown University Hospital

MedStar Health

DIABETIC FLOWSHEET (Adult)

FOR PRE-MEAL SQ INSULIN

FSBG = Fingerstick Blood Glucose

Date	Time	FSBG	Basal Dose (circle one), NPH, Lantus, Novolog Mix	Prandial Dose (circle one) NovoLog, Regular	Supplemental or Correctional Dose (circle one) NovoLog, Regular	Other	Initials
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Insulin Order Guidelines

1. Write for basal and nutritional insulin. Failure to give basal (long-acting) insulin coverage in a patient who is insulin deficient may result in diabetic ketoacidosis (DKA).
2. Choose the correction insulin algorithm and the frequency for it to be used.
3. Check the patient's BG pattern daily. Target BG goals are < 110 mg/dl pre meal and < 180 mg/dl peak post-meal. If the patient is not within these goals, adjust the scheduled insulin dose.

Situation	Recommendation
Type 1, NPO for > 24 hrs*	Use Insulin Drip.
Type 1, NPO for < 24 hrs*	Give reduced dose NPH bid or Lantus qd.
Type 2 on insulin, NPO *	Give reduced dose NPH bid or Lantus qd, If BG > 300, start insulin drip.
Type 1 or Type 2 on insulin, eating	Resume usual insulin regimen, adjust dose up or down as needed.
Type 1 or Type 2 initiating insulin therapy	Basal 0.4 units/kg (suggest as Glargine qd) Basal 0.3 units/kg for high risk for hypoglycemia (renal, cardiac, hepatic dysfunction or elderly). Mealtime: 0.1 unit/kg Novolog q ac
Type 2 on oral agents	D/C oral agents. If BG > 200 mg/dl, initiate insulin tx as above. If < 200 mg/dl use correction dose scale. After 2 days, add total daily insulin and give basal insulin qd
Type 1 or Type 2 on tube feedings	If feedings are bolus, give rapid-acting. insulin with each bolus. For continuous feeding give 50% of total insulin as Reg. Insulin q 6 hrs and 50% as qd Lantus. Hold Reg Insulin if tube feeding stopped or if BG < 100 mg/dl.
Type 1 or 2 on glucocorticoids	Increase both basal and prandial insulin. If BG > 250, consider insulin drip.
Type 1 or 2 on TPN	Use insulin drip for first 24 hrs. Take 75% of 24 hr insulin requirements and add to subsequent TPN bags. Continue insulin drip until stable.
Transition from insulin drip to sc insulin	Give 0.1 unit/kg as Novolog with meals. Give 40% of total daily insulin drip amount as basal insulin. The drip will shut itself off once BG falls < 70 mg/dl.

*For all patients who are insulin deficient, an insulin drip or basal (long acting) insulin must be given to prevent DKA, even when the patient is NPO.

Features of insulin deficiency: known type 1 DM; h/o pancreatic dysfunction; h/o wide BG fluctuations; h/o DKA; h/o insulin use > 5 yrs; h/o diabetes > 10 yrs.

This card was developed at Georgetown University Hospital by Stephen Clement, M.D.
Penny Smith, NP, CDE pager 542-8597 or 4-6251 Endocrine consult: 687-5081

Algorithms for Intensive Insulin Therapy of Diabetes in the Hospital - In the ICU and the Wards

Thomas Jefferson Hospital, Philadelphia, Pennsylvania
Critical Care Insulin Infusion Protocol
Submitted by Jeffrey Joseph, D.O.

PART A

All patients will have their blood glucose (BG) measured on admission to the ICU and 6 hourly thereafter. Should the blood glucose remain < 140mg/dl over the first 24 hours, blood glucose can measured daily and/or as clinically indicated.

INDICATIONS FOR INSULIN INFUSION:

Any ICU patient with blood glucose > 140 mg/dL x 2 consecutive measurements
Any ICU patient with DKA/HHNK

GOAL BLOOD GLUCOSE (BG):

80-140 mg/dL (while on insulin infusion)
70-140 mg/dL (off insulin infusion)

GENERAL GUIDELINES:

Use clinical judgment based on individual situation

Patients with BG ≤ 250 mg/dL must receive at least 5gm glucose/hour. If total D5W/D5NS infusion is running less than 5 gm/hr (100 cc/hr) or tube feeds at less than 40 cc/h, the patient should be on a D5 solution at 100cc/hr or a D10 solution at 50cc/hr. The purpose of a D5W infusion is to avoid hypoglycemia while on insulin infusion. When determining rate of infusion, must take into account other infusions with dextrose, enteral feeding, and fluid management issues.

MIXING INSULIN INFUSION:

Mix 100 units Regular insulin in 100 cc 0.9% saline (only Regular is used as IV insulin)

Insulin infusion is given as a piggy back with other IV fluids

Flush 20 cc of infusion through all IV tubing before infusion begins
(to saturate the insulin binding sites in the tubing)

INSULIN BOLUS (NOT for DKA/HHNK: call MD for specific orders):

Divide the initial BG by 100, then round to nearest 0.5 unit

INITIATING INSULIN INFUSION (NOT for DKA/HHNK: call MD for specific orders):

Divide the initial BG by 100, then round to nearest 0.5 unit

MONITORING:

Check BG q 1 hour until BG within goal (80-140 mg/dL) and stable for 4 consecutive hours, then:
Check BG q 2 hours if no significant change in clinical condition and nutritional intake
Consider resumption of q 1 hour BG monitoring if any of the following occurs:

a. Change in clinical condition
b. Change in insulin infusion rate
c. Initiation or cessation of pressor or steroid therapy
d. Initiation or cessation of renal replacement therapy (hemodialysis…)
e. Initiation, cessation or rate change of nutritional support (TPN, tube feeding…)

CHANGING THE INSULIN INFUSION RATE:

Follow the recommendations in the Table below:

Determine the current BG level and identify the appropriate column in the Table

Determine the rate of change (Δ) from the previous BG level
(difference between current BG and previous BG) and identify a row in the Table

Identify the cell which is the intersection of the column and the row chosen and follow the recommendations.

PART B

TABLE TO ADJUST INSULIN INFUSION RATE

Current BG ?BG	? 60	61-79	80-140	141-200	201-300	> 300
Dec by > 100	STOP‡	STOP*	STOP#	STOP#	STOP#	Dec by 50%
Dec by 50 - 100	STOP‡	STOP*	STOP#	Dec by 50%	Dec by 25%	No change
Dec by 25 - 49	STOP‡	STOP*	Dec by 25%	No change	No change	Inc by 25%
Dec or Inc 0 - 24	STOP‡	Dec by 25%	No change	Inc by 25%	Inc by 50%	Inc by 100%
Inc by 25 - 49	STOP‡	No change	Inc by 25%	Inc by 25%	Inc by 50%	Inc by 100%
Inc by ? 50	STOP‡	No change	Inc by 25%	Inc by 50%	Inc by 100%	Inc by 100%

‡ STOP infusion:

- If BG 40-60 SEE HYPOGLYCEMIA PROTOCOL, recheck BG q 15 minutes; when BG ≥ 80, restart infusion at 75% of previous rate
- If BG < 40 SEE HYPOGLYCEMIA PROTOCOL, recheck BG q 15 minutes; when BG ≥ 80, restart infusion at 50% of previous rate

* Stop infusion, recheck BG q 15 minutes; when BG ≥ 80 restart infusion at 75% of previous rate

\# Stop infusion for 15 minutes then restart at 50% of previous rate

PART C

HYPOGLYCEMIA PROTOCOL:

BG 40-70 mg/dL:

- Able to take oral: give 15 grams of oral glucose (glucose tablets or fast acting simple carbohydrates, like 4 oz orange juice)
- Unable to take oral and/or altered consciousness: 1mg glucagon SQ/IM or ½ Amp D50 IV (12.5 grams)

BG < 40 mg/dL:

- Able to take oral: give 15 grams of oral glucose (glucose tablets or fast acting simple carbohydrates, like 4 oz orange juice)
- Unable to take oral and altered consciousness: 1/2 Amp D50 IV (12.5 grams); if no IV access, give 1 mg glucagon SQ/IM
- Unable to take oral and conscious: 1 mg glucagon SQ/IM
- Always recheck the BG in 15 minutes; if BG still < 70 mg/dL, repeat the protocol. When BG normal (70-140 mg/dL), adjust baseline regimen (insulin and/or oral agents) in order to prevent recurrent hypoglycemia.

STOPPING TUBE FEEDS

Should the tube feeds be stopped for any reason (patient to leave the unit for a diagnostic test, high gastric residuals, feeding tube clogged, etc) the patient will be placed on a D5 solution (D5 NS, D5 ½ NS, D5 LR) and the insulin infusion shall be reduced by 50%. The blood glucose shall be monitored q hourly. Once the tube feeds are restarted (at full rate) allow at least 2 hours of overlap (D5 and tube feeds) before reducing/discontinuing the D5 solution

TRANSITION TO SQ INSULIN:

- The transition is best done when the patient is in a stable condition and able to take oral intake
- The transition must be individualized taking into account whether the patient is diabetic, on steroids, post-surgery, oral intake etc.
- An overlap between the infusion and the SQ insulin must be done; the duration of the overlap depends on the onset of action of the SQ insulin

Examples of transition to SQ insulin:

a. *For a type 1 diabetic:*

Establish 24 hour insulin requirements based on insulin infusion (extrapolate from average insulin infusion rate over last 6 8 hours if within stable range) and take 80 % of the total daily insulin needs: 2/3 is given in AM and 1/3 is given in PM:

- 2/3 of the AM insulin is given as NPH and 1/3 is given as Lispro or Regular
- 1/2 of the PM insulin is given as Lispro or Regular insulin at dinner and
- 1/2 is given as NPH at bedtime

b. *For a type 2 diabetic:*

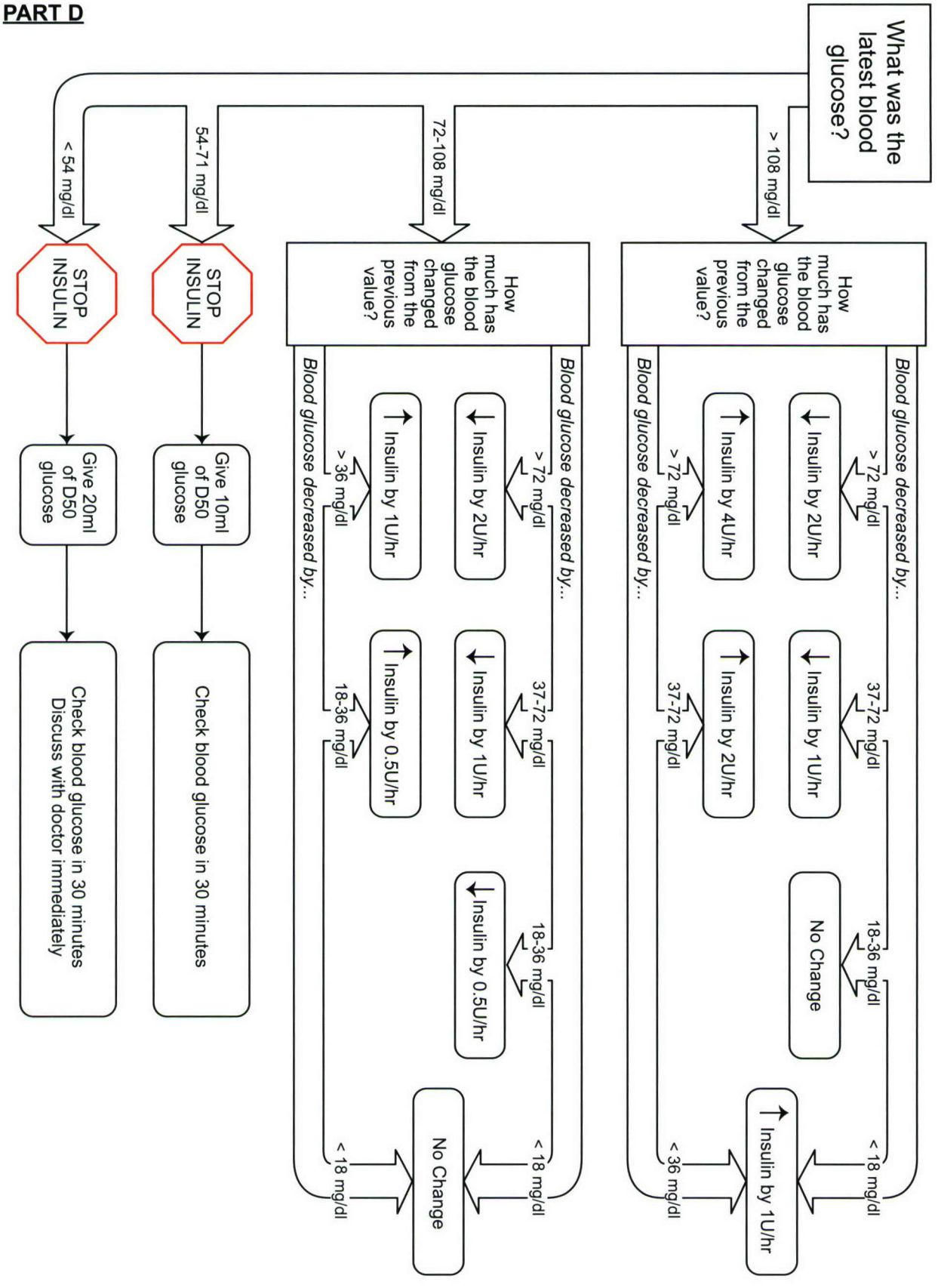
Establish 24 hour insulin requirements as above and take 80 % of the total daily insulin needs; a premixed insulin (70/30 or 75/25) is then given as 2/3 in the AM and 1/3 at dinner

SQ INSULIN SLIDING SCALE (Regular or Lispro):

Based on blood glucose monitoring QID (before meals and bedtime) or q6h (if NPO):

BG < 70 mg/dL: see hypoglycemia protocol
BG 70-140 mg/dL: no coverage
BG 141-200 mg/dL: 2 units
BG 201-250 mg/dL: 4 units
BG 251-300 mg/dL: 6 units
BG > 300 mg/dL: 8 units and call house officer

PART D


What was the latest blood glucose?
> 108 mg/dl
How much has the blood glucose changed from the previous value?
Blood glucose decreased by...
> 72 mg/dl
Insulin by 2U/hr
37-72 mg/dl
Insulin by 1U/hr
18-36 mg/dl
No Change
< 18 mg/dl
Insulin by 1U/hr
Blood glucose decreased by...
> 72 mg/dl
Insulin by 4U/hr
37-72 mg/dl
Insulin by 2U/hr
< 36 mg/dl
No Change
72-108 mg/dl
How much has the blood glucose changed from the previous value?
Blood glucose decreased by...
> 72 mg/dl
Insulin by 2U/hr
37-72 mg/dl
Insulin by 1U/hr
18-36 mg/dl
Insulin by 0.5U/hr
< 18 mg/dl
No Change
Blood glucose decreased by...
> 36 mg/dl
Insulin by 1U/hr
18-36 mg/dl
Insulin by 0.5U/hr
< 18 mg/dl
No Change
54-71 mg/dl
STOP INSULIN
Give 10ml of D50 glucose
Check blood glucose in 30 minutes
< 54 mg/dl
STOP INSULIN
Give 20ml of D50 glucose
Check blood glucose in 30 minutes
Discuss with doctor immediately

THE DIABETES TECHNOLOGY SOCIETY GRATEFULLY ACKNOWLEDGES EDUCATIONAL GRANTS FROM:

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- Novo Nordisk A/S
- sanofi aventis
- Amylim – Lilly
- Metrica, Inc.